



[Billing Code: 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-day comment request: NIH Information Collection Forms to Support Genomic Data Sharing for Research Purposes (OD)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Office of the Director, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) The quality, utility, and clarity of the information to be collected; and (4) Minimization of the burden of the collection of information from those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

TO SUBMIT COMMENTS AND FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dina N. Paltoo, PhD, MPH, Director, Genetics, Health, and Society Program, Office of Clinical Research and Bioethics Policy, Office of Science Policy, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892 or call non-toll-free number 301-496-9838 or E-mail your request, including your address to: GDS@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

PROPOSED COLLECTION: National Institutes of Health Information Collection Forms to Support Genomic Data Sharing for Research Purposes - 0925-0670 - Expiration Date 03/31/2016 – Revision - Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection: Sharing research data supports the NIH mission and is essential to facilitate the translation of research results into knowledge, products, and procedures that improve human health. The NIH has longstanding policies to make a broad range of research data, including genomic data, publicly available in a timely manner from the research activities that it funds. Genomic research data sharing is an integral element of the NIH mission as it facilitates advances in our understanding of

factors that influence health and disease, while also providing opportunities to accelerate research through the power of combining large and information-rich datasets. To promote robust sharing of human and non-human data from a wide range of large-scale genomic research and provide appropriate protections for research involving human data, the National Institutes of Health (NIH) issued the NIH Genomic Data Sharing Policy (GDS Policy). Human genomic data submissions and controlled-access are managed through a central data repository, the database of Genotypes and Phenotypes (dbGaP) which is administered by the National Center for Biotechnology Information (NCBI), part of the National Library of Medicine at NIH.

Under the GDS Policy, all investigators who receive NIH funding to conduct large-scale genomic research are expected to register studies with human genomic data in dbGaP, no matter which NIH-designated data repository will maintain the data. As part of the registration process, investigators must provide basic study information such as the type of data that will be submitted to dbGaP, a description of the study, and an institutional assurance (i.e. Institutional Certification) of the data submission which delineates any limitations on the secondary use of the data (e.g., data cannot be shared with for-profit companies, data can be used only for research of particular diseases).

Investigators interested in using controlled-access data for secondary research must apply through dbGaP and be granted permission from the relevant NIH Data Access Committee(s). As part of the application process, investigators and their institutions must provide information such as a description of the proposed research use of controlled-access datasets that conforms to any data use limitations, agree to the Genomic Data User Code of Conduct, and agree to the terms of access through a Data Use Certification

agreement. Requests to renew data access and reports to close out data use are similar to the initial data access request, requiring sign-off by both the requestor and the institution, but also ask for information about how the data have been used, and about publications, presentations, or intellectual property based on the research conducted with the accessed data as well as any data security issues or other data management incidents.

The NIH has developed online forms, available through dbGaP, in an effort to reduce the burden for researchers and their institutional officials to complete the study registration, data submission, data access, and renewal and closeout processes.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2,505.

Estimated Annualized Burden Hours

Type of Form	Number of Respondents	Number of Responses per Respondent	Average Time Per Response (in hours)	Total Annual Burden Hour
Study Registration and Data Submission				
Investigator Submitting Data	150	1	1	150
Institutional Official to Certify	150	1	30/60	75
Initial Data Access Request				
Investigator Requesting Data	633	2	45/60	950
Signing Official to Certify	633	2	30/60	633
Renewal and Close-out of Data Access				

Investigator Requesting Data	633	2	15/60	317
Signing Official to Certify	633	2	18/60	380

Dated: November 23, 2015.

Lawrence A. Tabak, .

Deputy Director,

National Institutes of Health.

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